Abbott

Declaration of Conformity

Certificate Identification: AIDD 3P36
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P36-20 3P36-25 3P36-30 3P36-35	17259	ARCHITECT AFP Reagent	Self-declared
3P36-01	38167	ARCHITECT AFP Calibrators	Self-declared
3P36-10	38166	ARCHITECT AFP Controls	Self-declared

Authorized European Representative (Name and Address)	N/A
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 07 Jun 14
Date Issued: 07 Jun 14
Supersedes: 13 Jan 2013

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 04 July 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 07 Jun 14

ARCHITECT SYSTEM

CEA Controls

en

REF 7K68-12

G2-6046/R03

C7K6R0

Read Highlighted Changes
Revised June 2012

INTENDED USE

The ARCHITECT CEA Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System (reagents, calibrators and instrument), when used for the quantitative measurement of Carcinoembryonic Antigen (CEA) in human serum or plasma. Refer to the ARCHITECT CEA reagent package insert for additional information.

CONTENTS

3 Bottles (8.0 mL each) of ARCHITECT CEA Controls (CONTROL L, CONTROL M, CONTROL H) containing CEA (human) prepared in phosphate buffer with protein (bovine) stabilizer. Preservative: Antimicrobial Agents.

The following concentration ranges may be used for individual replicate control specifications on the ARCHITECT System:

Control	Target Concentration CONC (ng/mL)	Range RANGE (ng/mL)
CONTROL L	5	3.3 - 6.8
CONTROL M	20	13.0 - 27.0
CONTROL H	100	65.0 - 135.0

Each laboratory should establish its own concentration ranges for new control lots at each control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days. Sources of variation that can be expected should be included in this study in order to be representative of future system performance. These may include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots
- Multiple processing modules
- Data points collected at different times of the day

These results should be applied to your laboratory's quality control practices.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use
- **CAUTION:** This product contains human sourced and/or potentially infectious components. The ARCHITECT Controls contain antigen derived from a human sourced cell line. Antigen is purified by chromatography prior to use. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens[1], Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

STORAGE

- ARCHITECT CEA Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C - 8°C

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline —Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

Distributed by Abbott Laboratories Abbott Park, IL 60064 USA
and
ABBOTT 65205 Wiesbaden, Germany

Abbott Ireland
Diagnostics Division
Finisklin Business Park
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June 2012

Abbott

Key to symbols used

GTIN	Global Trade Item Number
PRODUCT OF IRELAND	Product of Ireland
INFORMATION FOR USA ONLY	Information needed for United States of America only

ARCHITECT SYSTEM

CEA Calibrators

en

REF 7K68-02

G2-6047/R03

S7K6R0

Read Highlighted Changes
Revised June 2012

INTENDED USE

The ARCHITECT CEA Calibrators are for calibration of the ARCHITECT *i* System when used for the quantitative determination of Carcinoembryonic Antigen (CEA) in human serum and plasma. Refer to the ARCHITECT CEA reagent package insert for additional information.

CONTENTS

2 Bottles (4.0 mL each) of ARCHITECT CEA Calibrators. Calibrator 1 (CAL 1) contains phosphate buffer with protein (bovine) stabilizer; Calibrator 2 (CAL 2) contains CEA (human) prepared in phosphate buffer with protein (bovine) stabilizer. Preservative: Antimicrobial Agents.

The calibrators yield the following concentrations:

Calibrator	CEA Concentration (ng/mL)
CAL 1	0
CAL 2	10

STANDARDIZATION

Abbott manufactures internal reference standards for ARCHITECT CEA. These internal standards are referenced to the World Health Organization (W.H.O.) First International Standard 73/601 for CEA at each concentration level. ARCHITECT CEA Calibrators are manufactured by dilution and tested against these internal reference standards.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use
- **CAUTION:** This product contains human sourced and/or potentially infectious components. The ARCHITECT Calibrators contain antigen derived from a human sourced cell line. Antigen is purified by chromatography prior to use. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens[1]. Biosafety Level 2[2] or other appropriate biosafety practices[3,4] should be used for materials that contain or are suspected of containing infectious agents.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

STORAGE

- ARCHITECT CEA Calibrators are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C–8°C

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline —Third Edition*. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

ARCHITECT is a trademark of Abbott Laboratories in various jurisdictions.

Distributed by Abbott Laboratories Abbott Park, IL 60064 USA
and
ABBOTT 65205 Wiesbaden, Germany

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Diagnostics Division
Finisklin Business Park
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Ireland
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June 2012

Abbott

CE

Key to symbols used

GTIN	Global Trade Item Number
PRODUCT OF IRELAND	Product of Ireland
INFORMATION FOR USA ONLY	Information needed for United States of America only

Abbott

Declaration of Conformity

Certificate Identification:	AIDD 7K68
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Finisklin Business Park
	Sligo
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K68-22	30288	ARCHITECT CEA Reagent	Self-declared
7K68-27	30288	ARCHITECT CEA Reagent	Self-declared
7K68-32	30288	ARCHITECT CEA Reagent	Self-declared
7K68-35	30288	ARCHITECT CEA Reagent	Self-declared
7K68-02	38174	ARCHITECT CEA Calibrators	Self-declared
7K68-12	38173	ARCHITECT CEA Controls	Self-declared

Authorized European Representative (Name and Address)	N/A
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	Lorraine Whitney
Full Name:	Niall Plunkett	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	14 Jul 14	Date of Approval:	11 July 2014
Date Issued:	14 Jul 14	Place Issued:	AIDD Sligo
Supersedes:	30 Nov 2009	Effective (Date or Lot Number):	14 Jul 14

Abbott

Declaration of Conformity

Certificate Identification: 02K91 LC IRIS V4.2

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K91-20 2K91-23 2K91-25 2K91-27 2K91-28 2K91-29 2K91-35 2K91-38	60976	ARCHITECT CA 19-9xr Reagent Kit	Self-declared
2K91-01	38225	ARCHITECT CA 19-9xr Calibrators	Self-declared
2K91-10	38224	ARCHITECT CA 19-9xr Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Fujirebio Diagnostics, Incorporated 201 Great Valley Parkway Malvern, PA 19355, USA Fujirebio Diagnostics, Inc. Seguin, TX 78155, USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Elizabeth Leibham
Full Name: Elizabeth Leibham
Position: Quality Manager
Date of Approval: 5/11/2015
Date Issued: 5/28/2015
Supersedes: July 21,2014

Signature: Mary Ann Nuernberg
Full Name: MaryAnn Nuernberg
Position: Regulatory Affairs Manager
Date of Approval: 5/13/15
Place Issued: Abbott Laboratories DIAGNOSTICS DIVISION Abbott Park, IL
Effective (Date or Lot Number): 5/28/2014

ARCHITECT
CA 19-9XR Calibrators

REF 2K91-01

en
CA 19-9XR
2K91
604-001 8/14/R11
S2K910

Read Highlighted Changes: Revised October 2014.

INTENDED USE

The ARCHITECT CA 19-9XR Calibrators are for the calibration of the ARCHITECT iSystem when used for the quantitative determination of 1116-NS-19-9 reactive determinants in human serum or plasma.

Refer to the ARCHITECT CA 19-9XR reagent package insert and ARCHITECT System Operations Manual for additional information.

CONTENTS

6 Bottles (4 mL each) of ARCHITECT CA 19-9XR Calibrators.
Calibrator A contains TRIS buffer with protein (bovine) stabilizer.
Calibrators B - F contain 1116-NS-19-9 reactive determinants (human) prepared in TRIS buffer with protein (bovine) stabilizer.
Preservatives: sodium azide and ProClin 300.

The calibrators yield the following concentrations:

Calibrator	CA 19-9 Concentration (U/mL)
CAL A	0
CAL B	30
CAL C	100
CAL D	250
CAL E	600
CAL F	1200

STANDARDIZATION

CA 19-9 assay values are expressed as U/mL. A unit is a value related to a Fujirebio Diagnostics, Inc. maintained reference preparation. The calibrators for the ARCHITECT CA 19-9XR assay are manufactured volumetrically and are referenced to this standard prepared by Fujirebio Diagnostics, Inc. There is no Internationally recognized CA 19-9 standard available at this time.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use
- **CAUTION:** This product contains human-sourced and/or potentially infectious components. Calibrators B-F contain antigen derived from a human cell line. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1-4]

The following warnings and precautions apply to CAL A - CAL F	
WARNING	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

STORAGE

- Calibrators are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C – 8°C

PREPARATION FOR ANALYSIS

- Calibrators may be used immediately after removal from 2-8°C storage.
- Prior to use, mix by gentle inversion (5-10 times).
- After each use, tightly close the caps and return the calibrators to 2-8°C storage.

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition*. CLSI Document M29-A3. Wayne, PA: CLSI; 2005.

Key to Symbols

	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CAL A	Calibrator (A,B,C,D,E or F)
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
EC REP	Authorized Representative in the European Community
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF USA	Product of USA
REF	List Number
WARNING: SENSITIZER	Warning: May cause an allergic reaction.

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CE

PRODUCED FOR ABBOTT BY

Fujirebio Diagnostics Inc., Malvern, PA 19355 USA

Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

Revised October 2014.

Abbott

Abbott

Declaration of Conformity

Certificate Identification: 02K45 LC IRIS V4
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K45-20 2K45-23 2K45-25 2K45-28 2K45-35 2K45-38	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-01	38231	ARCHITECT CA 125 II Calibrators	Self-declared
2K45-10	38230	ARCHITECT CA 125 II Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Fujirebio Diagnostics, Incorporated 201 Great Valley Parkway Malvern, PA 19355, USA Fujirebio Diagnostics, Inc. Seguin, TX 78155, USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Elizabeth Leibham
Full Name: Elizabeth Leibham
Position: Quality Manager
Date of Approval: 5/11/2015
Date Issued: 5/28/2015
Supersedes: February 28, 2012

Signature: Mary Ceren Mutanbik
Full Name: Mary Ceren Mutanbik
Position: Regulatory Affairs Manager
Date of Approval: 5/14/2015
Place Issued: Abbott Laboratories Diagnostic Division Abbott Park, IL 60064 U.S.A.
Effective (Date or Lot Number): 5/28/2015

Abbott

Declaration of Conformity

Certificate Identification: AIDD 7K70
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K70-20	37286	ARCHITECT Total PSA Reagent Kit	**Annex II List B**
7K70-25	37286	ARCHITECT Total PSA Reagent Kit	**Annex II List B**
7K70-30	37286	ARCHITECT Total PSA Reagent Kit	**Annex II List B**
7K70-01	38208	ARCHITECT Total PSA Calibrators	**Annex II List B**
7K70-10	38207	ARCHITECT Total PSA Controls	**Annex II List B**

Authorized European Representative (Name and Address)	N/A
Notified Body (Name and Address)	UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey, GU3 1LR, United Kingdom
Approval Certificate No.	Certificate Number: 361.130510
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 14 May 14
Date Issued: 14 May 14
Supersedes: 20 May 2010

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Manager Regulatory Affairs
Date of Approval: 09 MAY 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 14 May 14

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of immunoassay based in vitro diagnostic devices for the detection and monitoring of infectious disease and other clinical markers

Device Classifications:
Annex II List A
Annex II List B

Device Descriptions and Model Type:
Please refer to Attachments: 1, 2, 3, 4, 5

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 5 attachments listing product references.

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here
UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 2 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
ARCHITECT Anti-HBs Controls 7C18-13	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-20	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-25	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-27	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-28	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-30	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-34	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-37	Annex II List A	-
ARCHITECT Anti-HBs Reagent kit 7C18-38	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Calibrators 9C94-01	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Controls 9C94-10	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit 9C94-25	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-35	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-29	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-41	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-39	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-42	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-33	Annex II List A	-
Alinity i HBsAg Calibrators 08P0801	Annex II List A	-
Alinity i HBsAg Controls 08P0810	Annex II List A	-

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 4 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type		Classification	G/UMDN Code
Alinity i HBsAg Reagent Kit	08P0822	Annex II List A	-
Alinity i Anti-HBs Reagent Kit	07P8932	Annex II List A	-
Alinity i Anti-HBs Reagent Kit	07P8957	Annex II List A	-
ARCHITECT Rubella IgM Reagent Kit 6C18-25		Annex II List B	-
ARCHITECT Rubella IgM Calibrator 6C18-01		Annex II List B	-
ARCHITECT Rubella IgM Controls 6C18-10		Annex II List B	-
ARCHITECT Rubella IgG Reagent Kit 6C17-26/36		Annex II List B	-
ARCHITECT Rubella IgG Calibrators 6C17-03		Annex II List B	-
ARCHITECT Rubella IgG Controls 6C17-13		Annex II List B	-
ARCHITECT Free PSA Reagent Kit 7K71-20/25		Annex II List B	-
ARCHITECT Free PSA Calibrators 7K71-01		Annex II List B	-
ARCHITECT Free PSA Controls 7K71-10		Annex II List B	-
ARCHITECT Total PSA Reagent Kit 7K70-20/25/30/35		Annex II List B	-
ARCHITECT Total PSA Calibrators 7K70-01		Annex II List B	-
ARCHITECT Total PSA Controls 7K70-10		Annex II List B	-
ARCHITECT CMV IgG Avidity Reagent Kit 3L46-25		Annex II List B	-
ARCHITECT CMV IgG Avidity Calibrator and Controls 3L46-11		Annex II List B	-
ARCHITECT CMV IgG Reagent Kit 6C15-20/25/30		Annex II List B	-
ARCHITECT CMV IgG Calibrators 6C15-01		Annex II List B	-
ARCHITECT CMV IgG Controls 6C15-10		Annex II List B	-

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and manufacture of immunoassay based in vitro diagnostic devices for the detection and monitoring of infectious disease and other clinical markers

Device Classifications:
Annex II List A
Annex II List B

Device Descriptions and Model Type:
Please refer to Attachments: 1, 2, 3, 4, 5

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 5 attachments listing product references.

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
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Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 1 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
ARCHITECT HBsAg Qualitative II Calibrators 2G22-01	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-25	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-30	Annex II List A	-
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit 2G23-25	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-01	Annex II List A	-
ARCHITECT HBsAg Calibrators 3M61-02	Annex II List A	-
ARCHITECT HBsAg Controls 6C36-10	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-22	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-27	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-32	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-29	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-34	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-35	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-43	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-44	Annex II List A	-
ARCHITECT HBsAg Reagent Kit 6C36-41	Annex II List A	-
ARCHITECT ABsAg Reagent Kit 6C36-42	Annex II List A	-
ARCHITECT Anti-HBs Calibrators 7C18-01	Annex II List A	-
ARCHITECT Anti-HBs Calibrators 7C18-03	Annex II List A	-
ARCHITECT Anti-HBs Controls 7C18-10	Annex II List A	-

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate
Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 2 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
ARCHITECT Anti-HBs Controls 7C18-13	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-20	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-25	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-27	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-28	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-30	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-34	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-37	Annex II List A	-
ARCHITECT Anti-HBs Reagent kit 7C18-38	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Calibrators 9C94-01	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Controls 9C94-10	Annex II List A	-
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit 9C94-25	Annex II List A	-
ARCHITECT HBsAg Qualitative II Reagent Kit 2G22-35	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-29	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-41	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-39	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-42	Annex II List A	-
ARCHITECT Anti-HBs Reagent Kit 7C18-33	Annex II List A	-
Alinity i HBsAg Calibrators 08P0801	Annex II List A	-
Alinity i HBsAg Controls 08P0810	Annex II List A	-

File Number A18074
Certificate Number 361.181012
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date October 12, 2018
Expiry Date June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 3 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
Alinity i HBsAg Reagent Kit 08P0852	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Calibrators 08P0901	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Controls 08P0910	Annex II List A	-
Alinity i HBsAg Confirmatory V.1 Reagent Kit 08P0922	Annex II List A	-
Alinity i HBsAg Qualitative II Calibrators 08P1001	Annex II List A	-
Alinity i HBsAg Qualitative II Controls 08P1010	Annex II List A	-
Alinity i HBsAg Qualitative II Reagent Kit 08P1022	Annex II List A	-
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit 08P1122	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8922	Annex II List A	-
Alinity i Anti-HBs Controls 07P8910	Annex II List A	-
Alinity i Anti-HBs Calibrators 07P8901	Annex II List A	-
Alinity i Anti-HBs Reagent Kit 07P8952	Annex II List A	-
Alinity s HBsAg Reagent Kit 06P0255	Annex II List A	-
Alinity s HBsAg Confirmatory Reagent Kit 06P0357	Annex II List A	-
Alinity s HBsAg Calibrator Kit 06P0202	Annex II List A	-
Alinity s HBsAg Assay Control Kit 06P0210	Annex II List A	-
Alinity s HBsAg Release Control Kit 06P0212	Annex II List A	-
ARCHITECT HBsAg Qualitative II Controls 2G22-10	Annex II List A	-
Alinity i HBsAg Qualitative II Reagent Kit 08P1032	Annex II List A	-
Alinity i HBsAg Reagent Kit 08P0832	Annex II List A	-

File Number	A18074	Cycle Start Date	June 24, 2016
Certificate Number	361.181012	Effective Date	October 12, 2018
Initial Issue Date	June 23, 2004	Expiry Date	June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 4 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type		Classification	G/UMDN Code
Alinity i HBsAg Reagent Kit	08P0822	Annex II List A	-
Alinity i Anti-HBs Reagent Kit	07P8932	Annex II List A	-
Alinity i Anti-HBs Reagent Kit	07P8957	Annex II List A	-
ARCHITECT Rubella IgM Reagent Kit 6C18-25		Annex II List B	-
ARCHITECT Rubella IgM Calibrator 6C18-01		Annex II List B	-
ARCHITECT Rubella IgM Controls 6C18-10		Annex II List B	-
ARCHITECT Rubella IgG Reagent Kit 6C17-26/36		Annex II List B	-
ARCHITECT Rubella IgG Calibrators 6C17-03		Annex II List B	-
ARCHITECT Rubella IgG Controls 6C17-13		Annex II List B	-
ARCHITECT Free PSA Reagent Kit 7K71-20/25		Annex II List B	-
ARCHITECT Free PSA Calibrators 7K71-01		Annex II List B	-
ARCHITECT Free PSA Controls 7K71-10		Annex II List B	-
ARCHITECT Total PSA Reagent Kit 7K70-20/25/30/35		Annex II List B	-
ARCHITECT Total PSA Calibrators 7K70-01		Annex II List B	-
ARCHITECT Total PSA Controls 7K70-10		Annex II List B	-
ARCHITECT CMV IgG Avidity Reagent Kit 3L46-25		Annex II List B	-
ARCHITECT CMV IgG Avidity Calibrator and Controls 3L46-11		Annex II List B	-
ARCHITECT CMV IgG Reagent Kit 6C15-20/25/30		Annex II List B	-
ARCHITECT CMV IgG Calibrators 6C15-01		Annex II List B	-
ARCHITECT CMV IgG Controls 6C15-10		Annex II List B	-

File Number A18074
Certificate Number 361.181012
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date October 12, 2018
Expiry Date June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

EC CERTIFICATE

Abbott Ireland Diagnostics Division

Finisklin Business Park
Sligo IRELAND

Attachment 5 of 5

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
ARCHITECT CMV IgM Reagent Kit 6C16-20/25/30	Annex II List B	-
ARCHITECT CMV IgM Calibrator 6C16-01	Annex II List B	-
ARCHITECT CMV IgM Controls 6C16-10	Annex II List B	-
Alinity i CMV IgG Reagent Kit 07P4222 / 07P4232	Annex II List B	-
Alinity i CMV IgG Calibrators 07P4201	Annex II List B	-
Alinity i CMV IgG Controls 07P4210	Annex II List B	-
Alinity i CMV IgM Reagent Kit 07P4422 / 07P4432	Annex II List B	-
Alinity i CMV IgM Calibrator 07P4401	Annex II List B	-
Alinity i CMV IgM Controls 07P4410	Annex II List B	-
Alinity i HBsAg Reagent Kit 08P0857	Annex II List A	-
Alinity i Rubella IgG Reagent Kit 08P4622 / 08P4632	Annex II List B	-
Alinity i Rubella IgG Calibrators 08P4601	Annex II List B	-
Alinity i Rubella IgG Controls 08P4610	Annex II List B	-
Alinity i Rubella IgM Reagent Kit 08P4722 / 08P4732	Annex II List B	-
Alinity i Rubella IgM Calibrator 08P4701	Annex II List B	-
Alinity i Rubella IgM Controls 08P4710	Annex II List B	-
Alinity i CMV IgG Avidity Reagent Kit 07P4322	Annex II List B	-
Alinity i CMV IgG Avidity Controls 07P4310	Annex II List B	-
Alinity s CMV IgG Qualitative Reagent Kit 06P1045	Annex II List B	-
Alinity s CMV IgG Qualitative Calibrator Kit 06P1002	Annex II List B	-
Alinity s CMV IgG Qualitative Assay Control Kit 06P1010	Annex II List B	-
Alinity s CMV IgG Qualitative Release Control Kit 06P1012	Annex II List B	-
Alinity i Free PSA Reagent Kit 07P9320 / 07P9330	Annex II List B	-
Alinity i Free PSA Calibrators 07P9301	Annex II List B	-
Alinity i Free PSA Controls 07P9310	Annex II List B	-
Alinity i Total PSA Reagent Kit 07P9220/07P9230	Annex II List B	-
Alinity i Total PSA Calibrators 07P9201	Annex II List B	-
Alinity i Total PSA Controls 07P9210	Annex II List B	-

File Number A18074
Certificate Number 361.181012
Initial Issue Date June 23, 2004

Cycle Start Date June 24, 2016
Effective Date October 12, 2018
Expiry Date June 23, 2019

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

IVDD A4 S3 FQ
00-MB-A0043 Issue: 15.0

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

Abbott

Declaration of Conformity

Certificate Identification: DoC-2G22-AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2G22-25	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-30	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-35	48321	ARCHITECT HBsAg Qualitative II Reagent Kit	Annex II List A
2G22-01	41999	ARCHITECT HBsAg Qualitative II Calibrators	Annex II List A
2G22-10	42000	ARCHITECT HBsAg Qualitative II Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	UL International (UK) Ltd Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey, GU3 1LR, United Kingdom
Notified Body number	0843
Approval Certificate No.	361
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Joe Murray	Signature:	Lorraine Whitney
Full Name:	Joe Murray	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	10 Jan 17	Date of Approval:	11 JAN 2017
Date Issued:	11 JAN 2017	Place Issued:	AIDD, Sligo
Supersedes:	13 Nov 2013	Effective (Date or Lot Number):	11 JAN 2017

Abbott

Declaration of Conformity

Certificate Identification: DOC-7C18 (re-standardised Mag-Sep) -AIDD Sligo
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park, Sligo, Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7C18-29	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-39	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-33	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-41	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-42	48316	ARCHITECT Anti-HBs Reagent Kit	Annex II List A
7C18-03	41997	ARCHITECT Anti-HBs Calibrators	Annex II List A
7C18-13	41998	ARCHITECT Anti-HBs Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	UL International (UK) Ltd Wonersh House The Guildway Old Portsmouth Road, Guildford, Surrey, GU3 1LR United Kingdom.
Notified Body number	0843
Approval Certificate No.	361
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division. Finisklin Business Park, Sligo, Ireland Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Joe Murray	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	24 Mar 17	Date of Approval:	22 Mar 17
Date Issued:	24 Mar 17	Place Issued:	AIDD, Sligo
Supersedes:	19 Dec 16	Effective (Date or Lot Number):	24 Mar 17

Abbott

Declaration of Conformity

Certificate Identification: DoC-6C32/7P24-All DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C32-20	48331	ARCHITECT HBeAg Reagent Kit (4x100 Tests)	Annex II List A
6C32-25	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-27	48331	ARCHITECT HBeAg Reagent Kit (1x100 Tests)	Annex II List A
6C32-37	48331	ARCHITECT HBeAg Reagent Kit (1x500 Tests)	Annex II List A
6C32-01	42007	ARCHITECT HBeAg Calibrators	Annex II List A
6C32-10	42008	ARCHITECT HBeAg Controls	Annex II List A
7P24-01	42007	ARCHITECT HBeAg Quantitative Calibrators	Annex II List A
7P24-10	42008	ARCHITECT HBeAg Quantitative Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00035**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	**Dr. Holger Kost**	Full Name:	**Mareike Nowak**
Position:	**Head of Quality**	Position:	**Assistant Manager Regulatory Affairs/ Site Operations Germany**
Date of Approval:	2018-02-26	Date of Approval:	2018-02-18
Date Issued:	2018-02-27	Place Issued:	65205 Wiesbaden, Germany
Supersedes:	13-Dec-2017	Effective (Date or Lot Number):	6C32-27: 86241LI00 6C32-37: 86242LI00

Abbott

Declaration of Conformity

Certificate Identification: DoC-6C34-All DELK

Legal Manufacturer's Name: Abbott GmbH & Co. KG

Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C34-20	48348	ARCHITECT Anti-HBe Reagent Kit (4x100 Tests)	Annex II List A
6C34-25	48348	ARCHITECT Anti-HBe Reagent Kit (1x100 Tests)	Annex II List A
6C34-35	48348	ARCHITECT Anti-HBe Reagent Kit (1x500 Tests)	Annex II List A
6C34-01	30871	ARCHITECT Anti-HBe Calibrator	Annex II List A
6C34-10	31014	ARCHITECT Anti-HBe Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00036**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany, Department Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Brämer

Full Name: **Dr. Christian Brämer**

Position: **Manager Quality**

Date of Approval: 19-April-2016

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs/ Site Operations Germany**

Date of Approval: 19/Apr/2016

Date Issued: 19/Apr/2016

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 04-May-2015

Effective (Date or Lot Number): 6C34-35 Lot# 64348L100

Abbott

Declaration of Conformity

Certificate Identification:	DoC 8L44 AII DELK
Legal Manufacturer's Name:	Abbott GmbH & Co. KG
Legal Manufacturer's Address:	Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8L44-25	48304	ARCHITECT Anti-HBc II Reagent Kit (1x100 Tests)	**Annex II List A**
8L44-30	48304	ARCHITECT Anti-HBc II Reagent Kit (4x500 Tests)	**Annex II List A**
8L44-35	48304	ARCHITECT Anti-HBc II Reagent Kit (1x500 Tests)	**Annex II List A**
8L44-01	41983	ARCHITECT Anti-HBc II Calibrator	**Annex II List A**
8L44-10	41984	ARCHITECT Anti-HBc II Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00117**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany, Department Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Brämer

Full Name: **Dr. Christian Brämer**

Position: **Manager Quality**

Date of Approval: 04-May-2015

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs/ Site Operations Germany**

Date of Approval: 04/May/2015

Date Issued: 04/May/2015

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 02-Jun -2014

Effective (Date or Lot Number): 04/May/2015

Abbott

Declaration of Conformity

Certificate Identification: DoC-6C33 All DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C33-22	48298	ARCHITECT Anti-HBc IgM Reagent Kit (4x100 Tests)	**Annex II List A**
6C33-27	48298	ARCHITECT Anti-HBc IgM Reagent Kit (1x100 Tests)	**Annex II List A**
6C33-02	41981	ARCHITECT Anti-HBc IgM Calibrators	**Annex II List A**
6C33-11	41982	ARCHITECT Anti-HBc IgM Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00033**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany, Department Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Dr. Holger Kost**
Position: **Head of Quality**
Date of Approval: 2017-07-10

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 06/Jul/2017
Date Issued: 13/Jul/2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 06-Nov-2015
Effective (Date or Lot Number): 6C33-22 Lot# 77176LI00
6C33-27 Lot# 77177LI00

Abbott

Declaration of Conformity

Certificate Identification: DoC-6C33 All DELK
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C33-22	48298	ARCHITECT Anti-HBc IgM Reagent Kit (4x100 Tests)	Annex II List A
6C33-27	48298	ARCHITECT Anti-HBc IgM Reagent Kit (1x100 Tests)	Annex II List A
6C33-02	41981	ARCHITECT Anti-HBc IgM Calibrators	Annex II List A
6C33-11	41982	ARCHITECT Anti-HBc IgM Controls	Annex II List A

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00033**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany, Department Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Dr. Holger Kost**
Position: **Head of Quality**
Date of Approval: 2017-07-10

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs**
Date of Approval: 06/Jul/2017
Date Issued: 13/Jul/2017
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 06-Nov-2015
Effective (Date or Lot Number): 6C33-22 Lot# 77176LI00
6C33-27 Lot# 77177LI00

Abbott

Declaration of Conformity

Certificate Identification: DOC-6C37-22/-27/-32/-37-All DLK

Legal Manufacturer's Name: Abbott GmbH & Co. KG

Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6C37-22	48366	ARCHITECT Anti-HCV Reagent Kit (4x100Tests)	**Annex II List A**
6C37-27	48366	ARCHITECT Anti-HCV Reagent Kit (1x100Tests)	**Annex II List A**
6C37-32	48366	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)	**Annex II List A**
6C37-37	48366	ARCHITECT Anti-HCV Reagent Kit (1x500 Tests)	**Annex II List A**
6C37-01	41972	ARCHITECT Anti-HCV Calibrator	**Annex II List A**
6C37-10	41973	ARCHITECT Anti-HCV Controls	**Annex II List A**

Authorized European Representative (name and address)	N/A
Notified Body (name and address)	LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom
Notified Body number	**0088**
Approval Certificate No.	**0088/0964174/00021**
Storage site of technical documentation (name and address)	Abbott GmbH & Co. KG, Max-Planck-Ring 2, 65205 Wiesbaden, Germany, Department Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Brämer

Full Name: **Dr. Christian Brämer**

Position: **Manager Quality**

Date of Approval: 04-May-2015

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs/ Site Operations Germany**

Date of Approval: 04/May/2015

Date Issued: 04/May/2015

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 30-Jun-2014

Effective (Date or Lot Number): 04/May/2015

Abbott

Declaration of Conformity

Certificate Identification: DOC-1P65-SD DLK OEM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1P65-35	61080	ARCHITECT Anti-CCP Reagent Kit (1x500 Tests)	**Self-declared**
1P65-25	61080	ARCHITECT Anti-CCP Reagent Kit (1x100 Tests)	**Self-declared**
1P65-10	54899	ARCHITECT Anti-CCP Controls	**Self-declared**
1P65-01	54898	ARCHITECT Anti-CCP Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Axis-Shield Diagnostics Ltd, Luna Place, The Technology Park, Dundee DD2 1XA, Scotland
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Brämer
Full Name: **Christian Brämer**
Position: **Manager Quality**
Date of Approval: 03-Mar-2016

Signature: Susanne Ulrich
Full Name: **Susanne Ulrich**
Position: **Senior Manager Regulatory Affairs, Site Operations, Germany**
Date of Approval: 3/ Mar/ 2016
Date Issued: 03/ March/ 2016.
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 17 Nov 2014
Effective (Date or Lot Number): 03/ March 2016

Abbott

Declaration of Conformity

Certificate Identification: ARCHITECT Solutions
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1L56-40	Not Available	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	Not Available	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	Not Available	ARCHITECT Trigger Solution	Self-declared
6C55-82	Not Available	ARCHITECT Trigger Solution	Self-declared
6E23-65	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	Not Available	ARCHITECT Multi-Assay Manual Diluent	Self-declared

Authorized European Representative (Name and Address)	N/A
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 07 JUL 14
Date Issued: 07 JUL 14
Supersedes: 15 Jun 2012

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 04 July 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 07 JUL 14

Abbott

Declaration of Conformity

Certificate Identification: ARCHITECT Solutions
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park
Sligo
Ireland

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1L56-40	Not Available	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	Not Available	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	Not Available	ARCHITECT Trigger Solution	Self-declared
6C55-82	Not Available	ARCHITECT Trigger Solution	Self-declared
6E23-65	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	Not Available	ARCHITECT Multi-Assay Manual Diluent	Self-declared

Authorized European Representative (Name and Address)	N/A
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

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This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 07 Jul 14
Date Issued: 07 JUL 14
Supersedes: 15 Jun 2012

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 04 July 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 07 JUL 14

Abbott

Declaration of Conformity

Certificate Identification:	ARCH Sys Acc LC	IRIS V3
Legal Manufacturer's Name:	Abbott Laboratories	
Legal Manufacturer's Address:	Diagnostics Division Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	NA	ARCHITECT Septum	Self-declared
4D19-01	NA	ARCHITECT Replacement Caps	Self-declared
7C14-01	NA	ARCHITECT Sample Cups	Self-declared
7C15-02	NA	ARCHITECT Reaction Vessels	Self-declared
7C15-03	NA	ARCHITECT Reaction Vessels	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature		Signature	Deborah Hinkley
Full Name:	_Lauren Sieber_	Full Name:	_Deborah Hinkley_
Position:	Product Quality Assurance Manager	Position	Regulatory Affairs Director
Date of Approval:	5/28/2015	Date of Approval:	5/29/2015
Date Issued:	06/02/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedes	June 13, 2013	Effective (Date or Lot Number):	06/02/2015